REMARKS

1. Status of the Office Action

Please note that the Office Action Summary specifies that the Office Action is a Final one, but the detailed/substantive Office Action does not so state, nor is a basis for finality set forth as per MPEP 706.07(a). Additionally, finality is not believed to be properly applicable because the Office Action contains new rejections predicated on U.S. Patent 4,485,816 to *Krumme* which are not necessitated by prior amendments. Therefore, it is believed that the checking of the "Final" box on the Summary was an inadvertent error, and the Office Action has been treated as a nonfinal one for purposes of this Response. If this understanding is incorrect, kindly reissue the Office Action with a statement of the basis for finality, as per MPEP 706.07(a).

2. Sections 1-2 of the Office Action: Foreign Priority and Cross-Reference to Prior Application

Please note that the present filing was made as per 35 USC §365(a)/(b), not §365(c), and thus it is believed that the priority GB applications should be present in the USPTO's file (since these priority applications should have been transmitted from the PCT International Bureau as per MPEP 1828/1893.03(c)). Additionally, it is believed that no statement is needed at the outset of the application since the application does not rely on 35 USC §120. If this understanding is incorrect, please advise. Please note that the priority is properly identified on the Official Filing Receipt of July 23, 2001, i.e., the application is a §371 of PCT/GB99/02544 filed August 3, 1999, which in turn claims priority to GB 9816800.8 and GB 9816802.4, both filed August 3, 1998.

3. Information Disclosure Statement

A new Information Disclosure Statement (with references and fee) is being mailed concurrently with the transmission of this Response. A copy is provided with this Response for your convenience. Kindly consider the references noted therein in all further actions.

4. Sections 3-5 of the Office Action: Acceptance of Amended Drawings, Specification, and Abstract

Acceptance of the amendments to the Drawings, Specification, and Abstract is noted and appreciated.

5. Section 6 of the Office Action: Rejection of Claims 51-63 under 35 USC §112(1)

These rejections are understood to mean that the Examiner believes that the claimed subject matter is not enabled by the specification. Kindly reconsider. As noted in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986):

> Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention, and is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive, and is determined as of the filing date of the patent application.... Furthermore, a patent need not teach, and preferably omits, what is well known in the art.

See also *Enzo Biochem Inc. v. Calgene Inc.*, 52 USPQ2d 1129, 1136 (Fed. Cir. 1999) ("[A]n enablement determination is made retrospectively, i.e., by looking back to the filing date of the patent application and determining whether undue experimentation would have been required to make and use the claimed invention at that time....") The enablement determination is, at least superficially, a simple one: regardless of the breadth of the disclosure, would one of ordinary skill know how to make and use the invention as claimed? See, e.g., *Bayer AG v. Schein Pharmaceuticals Inc.*, 64 USPQ2d 1001, 1006 (Fed. Cir. 2002) ("Because an enabling disclosure by definition turns upon the objective understanding of a skilled artisan, the enablement requirement can be met by reference to the knowledge of one of ordinary skill in the relevant art"); *In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) ("Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples"). See also MPEP 2164 *et seq.*

Here, it is submitted that the claimed subject matter is described in such terms that one of ordinary skill would be able to make and use the invention. The "first part(s)" and the "second part" are explicitly recited as being the parts of the device that contact the graft and artery

respectively; for example, considering the embodiment of FIG. 2, these "parts" comprise the ends of the wires (3). The "resilient member" is then explicitly recited as being the portion of the device connecting the first and second parts: looking again to the FIG. 2 embodiment, the "resilient member" is the length between the ends. Contrary to the assertions of the Office Action, it is indeed the "stored, mechanical, spring-type energy" in the resilient member – in the portion connecting the first and second parts – which biases the first and second parts towards each other. It is submitted that this subject matter is plainly enabled by the specification (see, e.g., page 5 lines 5-10, page 8 lines 16-22, etc.), and thus withdrawal of the rejections is requested.

6. The Amendments and the Support Therefor

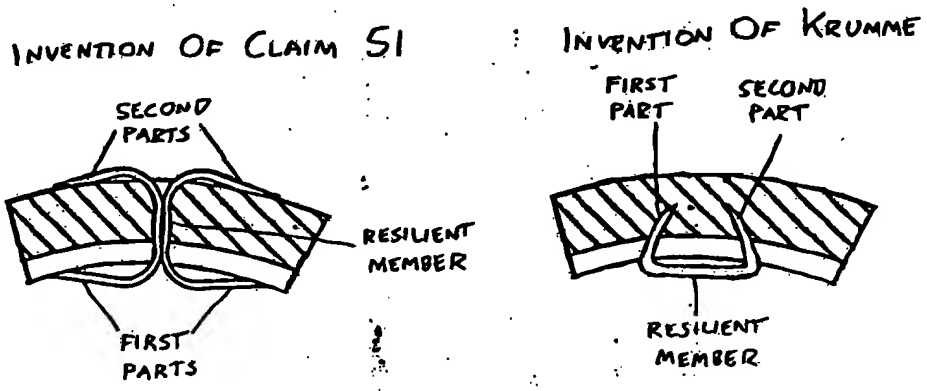
Five claims (52, 54, 65, 66, and 69) have been canceled, no new claims have been added, and claims 51, 55, 64, and 68 have been amended to leave claims 51, 53, 55-64, 67, 68, and 70 in the application.

Independent claim 51, which has been amended to incorporate claims 52 and 54, is submitted to be allowable for the following reasons.

Initially, it is submitted that claim 51 traverses all rejections under 35 USC §102(b) in view of U.S. Patent 4,485,816 to *Krumme* because *Krumme* does not disclose a fixator as recited in prior claim 52 (and now recited in claim 51), i.e., wherein a plurality of first parts and at least one second part are movable into an open configuration wherein they are at least substantially disposed along a common axis with the resilient member. This is shown by the lack of any 35 USC §102(b) rejections of claim 52 in view of *Krumme*. Additionally, looking to *Krumme*'s fixators which have a plurality of first parts and at least one second part – those fixators of FIGS 1a-1b and 5a-5b – the first parts, second parts, and their joining resilient member are not oriented along a common axis when in the open configuration; compare FIGS. 1a (open) and 1b (closed), and also review FIGS. 5a and 5b (both open).

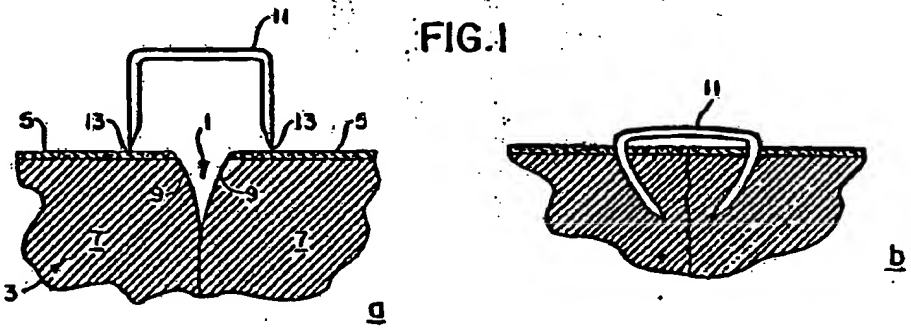
It is also submitted that there is no objectively ascertainable motivation to modify *Krumme* to meet the structure recited in claim 51, since there is no apparent advantage to making such a modification. This is particularly true when it is considered that the claimed fixator and that of

Krumme have an entirely different principle of operation: note that *Krumme*'s first and second parts each pierce a separate structure along separate axes, with the resilient member then joining the structures across their juncture (note, for example, FIGS. 1a and 1b and column 3 lines 13-31 and column 6 lines 44-49). Stated differently, consider if *Krumme* was used to radially pierce a graft and artery, as recited in claim 51 and depicted in FIG. 3: the first parts would not contact the graft and the second part would not contact the artery (as recited in claim 51), and rather both the first and second parts would contact the artery:



Note that *Krumme* is in essence a staple wherein its first and second parts/ends bend toward each other (as shown in FIGS. 1a-b):

FIG.1

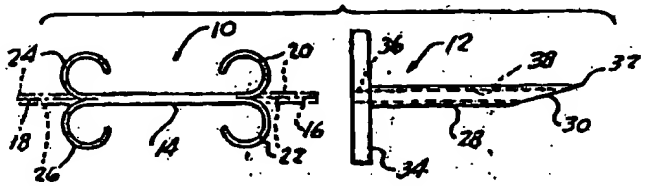


Consider that if *Krumme* was modified to contain the limitations of prior claim 52 (now recited in claim 51) wherein the first parts, at least one second part, and the resilient member were along a common axis, *Krumme* would not be operable for its intended purpose: it could not be inserted in the manner depicted by FIGS. 1a-b. It is therefore submitted that if the prior art is objectively

reviewed without prior knowledge of the invention (i.e., without hindsight), it is seen that the teachings of the art do not lead one to the invention claimed. See MPEP 2143.01 (subsection entitled "The Proposed Modification Cannot Render The Prior Art Unsatisfactory For Its Intended Purpose").

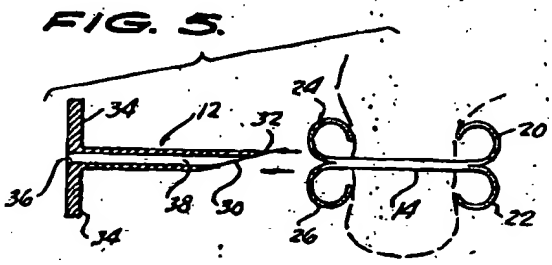
It is also submitted that claim 51 is allowable in view of U.S. Patent 3,527,223 to *Shein*. *Shein* does not disclose the feature of prior claim 54 (now incorporated in claim 51) that "wherein at least a portion of at least one of the first and second parts is sharpened to enable said part to pierce a graft and an artery." Rather, *Shein* utilizes a sharpened hollow insertion needle (12 in FIG. 1) which is used to pierce the earlobe, after which the ear stud 10 can be inserted through the needle 12 (and through the earlobe), with removal of the needle 12 then leaving the stud 10 in place:

FIG. 1.



The first and second parts/ends of *Shein*'s stud 10 are not sharpened, and there would not be any motivation to sharpen them because this would cause pain to the wearer (consider the effect in *Shein*'s FIG. 5 if the first and second parts/ends of *Shein*'s stud 10 were sharpened):

FIG. 5.



This is why *Shein* utilizes the separate hollow needle 12. Note that use of such a needle would be disadvantageous for installing a graft in an artery since it would punch a larger hole in the graft

and artery wall than is necessary to install the fixator; the end result is that one would have loose (and potentially leaky) fixation. In contrast, the claimed invention may both pierce and fix a graft on an artery with the fixator creating no greater hole than necessary.

Claims 53 and 55-63, which depend from claim 51, are submitted to be allowable for at least the same reasons as claim 51. Note that claim 55 is amended to correct dependency in view of the cancellation of claim 54.

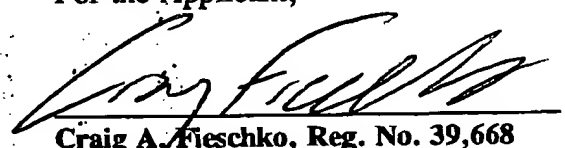
Independent claim 64, which is amended to incorporate claims 65 and 66, is submitted to be allowable for at least the same reasons as claim 51.

Independent claim 68, which is amended to incorporate claim 69 and to further clarify that the elongated member of the fixator is linearly oriented between its first and second ends when in the open configuration, is also submitted to be allowable for at least the same reasons as claim 51.

7. In Closing

If any questions regarding the application arise, please contact the undersigned attorney. Telephone calls related to this application are welcomed and encouraged. The Commissioner is authorized to charge any fees or credit any overpayments relating to this application to deposit account number 18-2055.

For the Applicant,



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ATTACHMENTS:

- PTO-2038 ($465)
- Information Disclosure Statement & Form 1449 (COPY)